

WHAT IS CLAIMED IS:

1. A pharmaceutical dosage form which comprises (a) a first drug which is at least one of promethazine and a pharmaceutically acceptable salt thereof and (b) at least one second drug, wherein the dosage form provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 70 % of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug.
2. The dosage form of claim 1, wherein the at least one second drug is selected from decongestants, antitussives, expectorants, mucus thinning drugs, analgesics and antihistamines.
3. The dosage form of claim 2, wherein the first drug comprises promethazine hydrochloride.
4. The dosage form of claim 1, wherein the at least one second drug comprises an antitussive.
5. The dosage form of claim 4, wherein the antitussive comprises at least one of codeine, dihydrocodeine, hydrocodone, dextromethorphan and pharmaceutically acceptable salts thereof.
6. The dosage form of claim 1, wherein the at least one second drug comprises a decongestant.
7. The dosage form of claim 6, wherein the second drug comprises at least one of phenylephrine, pseudoephedrine and pharmaceutically acceptable salts thereof.
8. The dosage form of claim 1, wherein the at least one second drug comprises an antihistamine.

9. The dosage form of claim 8, wherein the antihistamine comprises at least one of chlorpheniramine and pharmaceutically acceptable salts thereof.
10. The dosage form of claim 1, wherein the at least one second drug comprises an expectorant.
11. The dosage form of claim 10, wherein the expectorant comprises guaifenesin.
12. The dosage form of claim 2, wherein a plasma half-life of the at least one second drug is shorter than a plasma half-life of the first drug by at least about 3 hours.
13. The dosage form of claim 1, wherein a plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 4 hours.
14. The dosage form of claim 12, wherein the plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 6 hours.
15. The dosage form of claim 1, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 80 % of the period of a plasma concentration within the therapeutic range of the first drug.
16. The dosage form of claim 12, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 90 % of the period of a plasma concentration within the therapeutic range of the first drug.
17. The dosage form of claim 2, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 95 % of the period of a plasma concentration within the therapeutic range of the first drug.
18. The dosage form of claim 1, wherein the dosage form comprises a tablet.

19. The dosage form of claim 18, wherein the tablet has at least two layers.
20. The dosage form of claim 19, wherein the tablet is a bi-layered tablet.
21. The dosage form of claim 18, wherein the tablet comprises a matrix which comprises the first drug and has dispersed therein particles which comprise the at least one second drug.
22. The dosage form of claim 21, wherein the matrix has dispersed therein particles which comprise a second drug and a third drug.
23. The dosage form of claim 21, wherein the matrix has dispersed therein particles which comprise a second drug, a third drug and a fourth drug.
24. The dosage form of claim 21, wherein the matrix provides an immediate release of the first drug and the particles provide a controlled release of the at least one second drug.
25. The dosage form of claim 1, wherein the dosage form comprises one of a solution and a suspension.
26. The dosage form of claim 25, wherein the dosage form comprises a suspension having particles therein which provide a controlled release of the at least one second drug.
27. A bi-layered tablet which comprises a first layer and a second layer, the first layer comprising a first drug which is at least one of promethazine and a pharmaceutically acceptable salt thereof, and the second layer comprising at least one second drug which is selected from decongestants, antitussives, expectorants, mucus thinning drugs, analgesics and antihistamines, wherein the bi-layered tablet provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive

with at least about 70% of a period over which the bi-layered tablet provides a plasma concentration within a therapeutic range of the first drug.

28. The bi-layered tablet of claim 27, wherein the second layer comprises at least one of phenylephrine, pseudoephedrine, chlorpheniramine and pharmaceutically acceptable salts thereof.

29. The bi-layered tablet of claim 28, wherein the first layer comprises promethazine hydrochloride and the second layer comprises at least two of phenylephrine, pseudoephedrine, chlorpheniramine and pharmaceutically acceptable salts thereof.

30. The bi-layered tablet of claim 27, wherein the first layer comprises only promethazine or a pharmaceutically acceptable salt thereof as an active ingredient.

31. The bi-layered tablet of claim 29, wherein the first layer comprises only promethazine hydrochloride as an active ingredient.

32. The bi-layered tablet of claim 30, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 80 % of the period of a plasma concentration within the therapeutic range of the first drug.

33. The bi-layered tablet of claim 31, wherein the period of a plasma concentration within a therapeutic range of the at least one second drug is coextensive with at least about 90 % of the period of a plasma concentration within a therapeutic range of the first drug.

34. The bi-layered tablet of claim 30, wherein the first layer is an immediate release layer.

35. The bi-layered tablet of claim 27, wherein the second layer is a controlled release layer.

36. The bi-layered tablet of claim 34, wherein the first layer contains from about 0.1 mg to about 90 mg of promethazine hydrochloride.

37. The bi-layered tablet of claim 36, wherein the first layer contains from about 25 mg to about 50 mg of promethazine hydrochloride.

38. The bi-layered tablet of claim 36, wherein the second layer is a controlled release layer and contains at least one of (i) from about 0.1 mg to about 16 mg of chlorpheniramine maleate or an equivalent amount of at least one other pharmaceutically acceptable salt of chlorpheniramine; (ii) from about 1 mg to about 90 mg of phenylephrine hydrochloride or an equivalent amount of at least one other pharmaceutically acceptable salt of phenylephrine; and (iii) from about 1 mg to about 240 mg of pseudoephedrine hydrochloride or an equivalent amount of at least one other pharmaceutically acceptable salt of pseudoephedrine.

39. A multi-layered tablet which comprises at least a first layer and a second layer, wherein the first layer comprises at least one of promethazine and a pharmaceutically acceptable salt thereof and the second layer is a controlled release layer and comprises at least one drug which is selected from decongestants, antitussives, expectorants, mucus thinning drugs, analgesics and antihistamines.

40. The multi-layered tablet of claim 39, wherein the first layer is an immediate release layer.

41. The multi-layered tablet of claim 40, wherein the first layer comprises promethazine hydrochloride.

42. The multi-layered tablet of claim 39, wherein the first layer does not contain any active ingredient which is different from promethazine or a pharmaceutically acceptable salt thereof.

43. The multi-layered tablet of claim 39, wherein the second layer comprises at least one of codeine, dihydrocodeine, hydrocodone, dextromethorphan, phenylephrine, pseudoephedrine, guaifenesin, chlorpheniramine and pharmaceutically acceptable salts thereof.

44. The multi-layered tablet of claim 40, wherein the second layer comprises at least two of codeine, dihydrocodeine, hydrocodone, dextromethorphan, phenylephrine, pseudoephedrine, guaifenesin, chlorpheniramine and pharmaceutically acceptable salts thereof.

45. The multi-layered tablet of claim 39, wherein the at least one drug in the second layer has a plasma half-life which is shorter by at least about 3 hours than a plasma half-life of the at least one of promethazine and a pharmaceutically acceptable salt thereof in the first layer.

46. The multi-layered tablet of claim 39, wherein the first layer comprises promethazine hydrochloride and the tablet provides a plasma concentration within a therapeutic range of the at least one drug in the second layer over a period which is coextensive with at least about 80 % of the period over which the multi-layered tablet provides a plasma concentration within a therapeutic range of promethazine hydrochloride.

47. The multi-layered tablet of claim 46, wherein the at least one drug in the second layer comprises one or more of phenylephrine, pseudoephedrine, chlorpheniramine and pharmaceutically acceptable salts thereof.

48. The multi-layered tablet of claim 39, wherein the layers are discrete zones which are arranged adjacent to each other.

49. The multi-layered tablet of claim 39, wherein the second layer is partially or completely surrounded by the first layer.

50. The multi-layered tablet of claim 49, wherein the second layer is coated with the first layer.

51. A liquid dosage form which comprises (a) at least one of promethazine and a pharmaceutically acceptable salt thereof and (b) at least one drug which is selected from decongestants, expectorants, mucus thinning drugs, antitussives, analgesics and antihistamines, wherein the liquid dosage form provides a plasma concentration within a therapeutic range of component (b) over a period which is coextensive with at least about 70 % of a period over which the liquid dosage form provides a plasma concentration within a therapeutic range of component (a).

52. The liquid dosage form of claim 51, wherein the liquid dosage form comprises a suspension.

53. The liquid dosage form of claim 52, wherein at least a part of component (b) is present as a complex with a complexing agent.

54. The liquid dosage form of claim 53, wherein at least a part of component (a) is present as a complex with a complexing agent.

55. The liquid dosage form of claim 53, wherein the complexing agent comprises an ion-exchange resin.

56. The suspension of claim 55, wherein the ion-exchange resin comprises sodium polystyrene sulfonate.

57. The suspension of claim 53, wherein the suspension comprises particles of a complex of at least a part of component (b) with an ion-exchange resin, which particles are provided, at least in part, with a controlled release coating.

58. The suspension of claim 57, wherein the controlled release coating comprises an organic polymer.

59. The suspension of claim 58, wherein the organic polymer comprises a polyacrylate.

60. A method of concurrently alleviating a condition which can be alleviated by administration of promethazine and at least one other condition which can be alleviated by administration of a drug which is at least one of a decongestant, antitussive, expectorant, mucus thinning drug, analgesic and antihistamine, wherein the method comprises administering the pharmaceutical dosage form of claim 1 to a subject in need thereof.

61. A method of concurrently alleviating a condition which can be alleviated by administration of promethazine and at least one other condition which can be alleviated by administration of a drug which is at least one of a decongestant, antitussive, expectorant, mucus thinning drug, analgesic and antihistamine, wherein the method comprises administering the multi-layered tablet of claim 39 to a subject in need thereof.

62. The method of claim 61, wherein the condition which can be alleviated by administration of promethazine comprises an allergic reaction.

63. The method of claim 62, wherein the multi-layered tablet is administered not more than about three times per day.

64. The method of claim 61, wherein the multi-layered tablet is administered not more than about twice per day.



65. A method of concurrently alleviating a condition which can be alleviated by administration of promethazine and at least one other condition which can be alleviated by administration of a drug which is at least one of a decongestant, antitussive, expectorant, mucus thinning drug, analgesic and antihistamine, wherein the method comprises administering the liquid dosage form of claim 51 to a subject in need thereof.

66. A process of making the pharmaceutical dosage form of claim 1, wherein the method comprises preparing a first composition which comprises the first drug and a second composition which comprises the at least one second drug, and combining the first and the second compositions to form the dosage form.

67. The process of claim 66, wherein the first and second compositions are combined by using a tablet press.

68. A pharmaceutical dosage form which comprises (a) a first drug which is an antihistamine and has a first plasma half-life and (b) at least one second drug which is selected from decongestants, antitussives, expectorants, mucus thinning drugs, analgesics and antihistamines and has a second plasma half-life which differs from the first plasma half-life by at least about 3 hours, wherein the dosage form provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 70 % of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug.

69. The dosage form of claim 68, wherein the first plasma half-life is longer by at least about 4 hours than the plasma half-life of the at least one second drug.

70. The dosage form of claim 69, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 80 % of the period over which the dosage form provides a plasma concentration within the therapeutic range of the first drug.

71. The dosage form of claim 68, wherein the dosage form comprises a bi-layered tablet.

72. The dosage form of claim 70, wherein the first plasma half-life is at least about 8 hours.

73. The dosage form of claim 68, wherein the dosage form is associated with instructions to administer the dosage form three or fewer times per day.

74. The dosage form of claim 71, wherein the dosage form is associated with instructions to administer the dosage form three or fewer times per day.